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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 09/778,496 | 02/07/2001 | David M. Lubman | UM-06106 | 8813 |
| 23535 | 7590 | 05/18/2004 | EXAMINER | |
| MEDLEN & CARROLL, LLP | | | MAHATAN, CHANNING | |
| 101 HOWARD STREET | | | | |
| SUITE 350 | | | ART UNIT | PAPER NUMBER |
| SAN FRANCISCO, CA 94105 | | | 1631 | |

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--------------------|------------------|--|
| Application No. | 09/778,496 | |
| Examiner | LUBMAN ET AL. | |
| Channing S Mahatan | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 January 2004.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,8-24 and 26-37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-6,8-24 and 26-37 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 Sheet.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 05 January 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-6, 8-24, and 26-37.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 21 and 34 recite the phrase "ESI oa TOF" which is vague and indefinite. It is unclear as what Applicants' regard as "oa". Clarification of the claim language is requested.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-6, 8-20, 22-24, and 26-33 under 35 U.S.C. § 103(a) as being unpatentable over Chong et al. taken in view of Richmond et al. (High-throughput flow injection analysis-mass spectrometry with network delivery of colour rendered results: the characterisation of liquid chromatography fractions, Journal of Chromatography. 1999, Volume 835, pages 29-39) are maintained for reasons of record.

Applicants' argue: 1) Richmond provides no teaching that the display methods that Richmond applies to chemical samples be used in the display of protein samples; 2) Chong does not suggest the need for an alternate display method; 3) neither Chong et al. nor Richmond et al., alone or in combination, teach the claim element of a protein profile map that displays protein abundance and mass of a separated protein sample; and 4) neither Chong et al. or Richmond et al. teaches the claim element of a switchable, multichannel valve". Applicants' arguments are found unpersuasive for the reasons below.

Although Chong et al. does not suggest the need for an alternate display method, Richmond et al., however, states colored computer screen pictures and 3D maps provide quick and easy way of delivering liquid chromatography (i.e. high performance liquid chromatography/HPLC) data to laboratories (page 39, lines 17-23). Chong et al. teaches the profiling of proteins from whole cell lysates such that protein fractions are separated by non-

porous reverse phase high-performance liquid chromatography (HPLC) and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS) (Abstract; page 1987, column 1, lines 5-7, and page 1993, Column 1, lines 6-10), wherein the protein profile maps of Chong et al. indicate molecular weight (mass) and protein expression (abundance) (page 1987, column 1, lines 7-35). Chong et al. utilizes the Beckman System Gold HPLC having a programmable solvent delivery module with a dual pump (switchable, multichannel valve) and the System Control Center permits the control of the pump and external modules directly (i.e. additional pumps, therefore, multi-channel valves) (page 1989, column 1, lines 17-21). Chong et al. depicts the protein profile maps side-by-side in Figure 1 (claims 1, 23, and 28).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Chong et al. in view of Richmond protein profiling of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS), with Richmond et al., graphical display of color intensity bands representing (intensity/mass) from liquid chromatography information side-by-side.

Claims 35-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chong et al. taken in view of Richmond et al. (High-throughput flow injection analysis-mass spectrometry with network delivery of colour rendered results: the characterisation of liquid chromatography fractions, Journal of Chromatography. 1999, Volume 835, pages 29-39) further in view of Pandey et al.

Chong et al. taken in view of Richmond et al. is herein applied as above and from the previous office action, mailed 01 October 2003. However, Chong et al. and/or Richmond et al. fail to utilize differential display to depict protein profile maps.

Pandey et al. describes the use of differential display in proteomics for comparison of protein levels (Abstract). The process of applying differential display to mass spectrometry data is described and illustrated (page ; Figures 1 and 3). Further, protein profile maps are depicted side-by-side (Figures 1 and 3).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Chong et al., protein profiling of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS), with Richmond et al., graphical display of colour intensity bands representing (intensity/mass) from liquid chromatography information side-by-side, further with Pandey et al. differential display of protein data from mass spectrometry. Since Pandey et al. describes the application of differential display in the field of proteomics, particularly mass spectrometry protein profile maps.

BENEFIT CLAIM

With regard to the above 35 U.S.C. § 103 Rejection (i.e. claims 35-37) pertaining to Pandey et al. Applicants claim to the benefit of Provisional Application Number 60/180,911 (08 February 2000) for “displaying a differential display protein map...” is denied, since there does not appear to be any disclosure or contemplation for “displaying a differential display protein map...”.

INFORMATION DISCLOSURE STATEMENT

The Righetti et al. reference in the 'Information Disclosure Statement', filed 05 January 2004, was not considered due to the absence of said reference and has been lined through. Should Applicants desire consideration of the missing reference a new 'Information Disclosure Statement' accompanied by a copy of said reference is requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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Art Unit: 1631

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Date: *May 13, 2004*
Examiner Initials: *CSW*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER

5/13/04
MSA